

Listing of Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

1-13. (Cancelled)

14. (Previously Presented) A flow-through assay device for detecting the presence or quantity of an analyte residing in a test sample, said flow-through assay device comprising a porous membrane in communication with optical detection probes conjugated with a first antibody specific for the analyte, said porous membrane defining:

a competitive zone that contains a second antibody immobilized on said porous membrane that is complexed to an antigen containing an optically detectable substance prior to the application of a test sample to the device, said antigen being identical to or an analog of the analyte and said optically detectable substance being capable of producing a competitive signal when contained within said competitive zone; and

a detection zone within which a third antibody is immobilized that is configured to bind to complexes formed between the analyte and said conjugated optical detection probes to produce a first detection signal, said third antibody also being configured to bind to said antigen from said competitive zone to produce a second detection signal, wherein the amount of the analyte within the test sample is determined from said competitive signal, and at least one of said first detection signal and said second detection signal.

15. (Original) A flow-through assay device as defined in claim 14, wherein said optical detection probes and said optically detectable substance of said antigen each comprise a visual label.

16. (Original) A flow-through assay device as defined in claim 14, wherein said optical detection probes and said optically detectable substance of said antigen each comprise a luminescent compound.

17. (Original) A flow-through assay device as defined in claim 16, wherein said detection probes emit a signal at a different wavelength than said optically detectable substance of said antigen.

18. (Original) A flow-through assay device as defined in claim 14, wherein said porous membrane further defines a calibration zone that is configured to produce a calibration signal.

19. (Currently Amended) A flow-through assay device as defined in claim 14, wherein the amount of the analyte within the test sample is capable of being determined from one or both of the following formulae:

$$\frac{D_1 + x}{\text{when } x > 0, D_1 = D_{1\max}}$$

wherein,

$$x = C_{1\max} - C_1;$$

$C_{1\max}$ is a predetermined maximum intensity for said competitive signal;

C_1 is the intensity of said competitive signal;

D_1 is the intensity of said first detection signal; and

$D_{1\max}$ is a predetermined maximum intensity for said first detection signal; or

$$\frac{D_1 + D_2}{\text{when } D_2 > 0, D_1 = D_{1\max}}$$

wherein,

D_1 is the intensity of said first detection signal;

D_{1max} is a predetermined maximum intensity for said first detection signal; and

D_2 is the intensity of said second detection signal

~~$D_{sub.1} + x$, when $x > 0$, $D_{sub.1} = D_{sub.1max}$ wherein, $x = C_{sub.1max} - C_{sub.1}$;~~

~~$C_{sub.1max}$ is a predetermined maximum intensity for said competitive signal; $C_{sub.1}$ is the intensity of said competitive signal; $D_{sub.1}$ is the intensity of said first detection signal; and $D_{sub.1max}$ is a predetermined maximum intensity for said first detection signal; or $D_{sub.1} + D_{sub.2}$, when $D_{sub.2} > 0$, $D_{sub.1} = D_{sub.1max}$ wherein, $D_{sub.1}$ is the intensity of said first detection signal; $D_{sub.1max}$ is a predetermined maximum intensity for said first detection signal; and $D_{sub.2}$ is the intensity of said second detection signal.~~

20. (Withdrawn) A method for detecting the presence or quantity of an analyte residing in a test sample, said method comprising:

i) providing a flow-through assay device comprising a porous membrane in communication with detection probes conjugated with a first antibody specific for the analyte, said porous membrane defining:

a) a competitive zone within which is immobilized a second antibody complexed to an antigen containing an optically detectable substance, said antigen being identical to or an analog of the analyte and said optically detectable substance being capable of producing a competitive signal when contained within said competitive zone; and

b) a detection zone within which a third antibody is immobilized that is configured to bind to complexes formed between the analyte and said conjugated optical detection probes to produce a first detection signal, said third antibody also

being configured to bind to said antigen from said competitive zone to produce a second detection signal;

ii) contacting a test sample containing the analyte with said conjugated detection probes;

iii) measuring the intensity of said competitive signal at said competitive zone, and the intensity of said first and second detection signals at said detection zone; and

iv) determining the amount of the analyte within the test sample from one or both of the following formulae:

$$D_1 + x,$$

$$\text{when } x > 0, D_1 = D_{1\max}$$

wherein,

$$x = C_{1\max} - C_1;$$

$C_{1\max}$ is a predetermined maximum intensity for said competitive signal;

C_1 is the intensity of said competitive signal;

D_1 is the intensity of said first detection signal; and

$D_{1\max}$ is a predetermined maximum intensity for said first detection signal; or

$$D_1 + D_2,$$

$$\text{when } D_2 > 0, D_1 = D_{1\max}$$

wherein,

D_1 is the intensity of said first detection signal;

$D_{1\max}$ is a predetermined maximum intensity for said first detection signal; and

D_2 is the intensity of said second detection signal.

21. (Withdrawn) A method as defined in claim 20, wherein said optical detection probes and said optically detectable substance of said antigen each comprise a visual label.

22. (Withdrawn) A method as defined in claim 20, wherein said optical detection probes and said optically detectable substance of said antigen each comprise a luminescent compound.

23. (Withdrawn) A method as defined in claim 22, wherein said detection probes emit a signal at a different wavelength than said optically detectable substance of said antigen.

24. (Withdrawn) A method as defined in claim 20, further comprising exciting said conjugated optical detection probes at said detection zone to produce said first detection signal.

25. (Withdrawn) A method as defined in claim 24, further comprising exciting said optically detectable substance at said competitive zone to produce said competitive signal.

26. (Withdrawn) A method as defined in claim 25, further comprising exciting said optically detectable substance at said detection zone to produce said second detection signal.

27. (Withdrawn) A method as defined in claim 20, wherein said porous membrane further defines a calibration zone that is configured to produce a calibration signal.

28. (Withdrawn) A method as defined in claim 27, further comprising generating a calibration curve by plotting said competitive signal and said first and second

detection signals as calibrated by said calibration signal for a plurality of predetermined analyte concentrations.

29. (New) A flow-through assay device as defined in claim 14, wherein the intensity of the competitive signal is at a maximum value when no analyte is present within the test sample.

30. (New) A flow-through assay device as defined in claim 14, wherein the conjugated detection probes bind to the antigen within the competitive zone to produce a second competitive signal when no analyte is present within the test sample.

31. (New) A flow-through assay device as defined in claim 14, wherein the intensity of the first detection signal reaches a maximum value at or near the saturation concentration of the analyte within the test sample.